K040951

JUL 2 2 2004

510 (k) Summary of Safety and Effectiveness for PatXfer RT

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
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Contact Person: Mr. Rainer Birkenbach

Summary Date: April 5, 2004

Device Name:

Trade name: PatXfer RT
Common/Classification Name: System, Image Processing, Radiological

Predicate Device:

PatXfer 5.0 (K021583)

Device Classification Name: Picture archiving and Communication System
Regulatory Class: Class II

Intended Use:

PatXfer RT provides capabilities for the acceptance, transfer, display, storage, and digital processing of medical images and objects according to the DICOM RT standard and according to the BrainLAB proprietary data format.

This includes functions for performing operations related to image manipulation, enhancement, compression, and quantification. The integrity of the original data is maintained.

Device Description:

PatXfer RT interfaces between medical devices and provides the patient data for treatment planning or verification.
The application transfers, displays, stores, and processes data received according to the ACR-NEMA standard (DICOM 3.0) or according to the BrainLAB proprietary data format. DICOM RT data are converted into the BrainLAB proprietary data format and vice-versa for further data processing.

PatXfer RT supports Dicom RT data and BrainLAB's proprietary data formats from digital storage media, such as network archive, optical disk or CD-ROM.

To keep the application as user-friendly as possible only the necessary information for the intended procedures are displayed. The patient, image series, and images will be displayed and can be selected and processed.

PatXfer RT creates a history log-file including all the software actions to import the data and can be controlled with the mouse or by touchscreen monitor.

Typical users of the system are trained professionals, including but not limited to physicians, nurses, and technicians.

Substantial equivalence

A risk analysis was conducted for PatXfer RT and all hazards were mitigated to as low as reasonable possible (ALARP) and found to be acceptable. The Verification showed that PatXfer RT is safe and effective for its intended use.

PatXfer RT has been verified and validated according to BrainLAB's procedures for product design and development and found to be substantially equivalent with BrainLAB medical devices such as PatXfer 5.0 (K021583). The validation proves the safety and effectiveness of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstraße 8
85551 Heimstetten
GERMANY

Re: K040931
Trade/Device Name: PatXfer RT
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 6, 2004
Received: July 8, 2004

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040931

Device Name: PatXfer RT

Indications For Use:

PatXfer RT provides capabilities for the acceptance, transfer, display, storage, and digital processing of medical images and objects according to the DICOM RT standard and according to the BrainLAB proprietary data format.

This includes functions for performing operations related to image manipulation, enhancement, compression, and quantification. The integrity of the original data is maintained.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040931